

### REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and these remarks.

Cancellation of claims 4 and 5 is requested, without prejudice or disclaimer. Claim 2 has been amended to prescribe more clearly the steps of the inventive methodology, as well as to incorporate salient recitations from claims 4 and 5. No new matter is added.

Upon entry of this response, claims 2, 6-12, 15, 16, and 18-27 will be pending.

#### **I. The claims recite all essential steps of the claimed method**

Claims 2, 4-12, 15, 18-19, 24-25, and 27 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly omitting essential steps. In particular, the Examiner contends that the claims do not recite binding of the affinity-specific molecules to the gram-negative or gram-positive bacteria.

In other words, the Examiner is heard to say that the claims are unclear on how the harmful substance can be retained within the column. Yet independent claim 2 presently recites three steps, which are abbreviated here: (a) passing the blood through a fluidized adsorption column assembly containing particles with specific affinity; (b) contacting the harmful substances in the blood to the affinity specific molecules such that the affinity specific molecules bind the harmful substances; and c) retaining the harmful substances bound to the affinity specific molecule while the blood exits the column. Claim 27 has similar steps but further recites reinfusing the blood.

The claims thus prescribe that the harmful substances are bound to the affinity specific molecules and thus are retained in the column. Because this interaction is made explicit, Applicants respectfully request that the rejection be withdrawn.

## **II. Zimmerman does not anticipate the claims**

Claims 2, 4-8, 11-12, 15-21, and 24-27 stand rejected for alleged anticipation by U.S. Pat. No. 6,090,292 ("Zimmerman"). Applicants respectfully traverse this rejection.

An anticipation rejection requires a showing that each limitation of a claim is found in a single reference, practice, or device. *See In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985). In order for a reference to be anticipatory, it must "be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." *See In re Paulsen*, 30 F.3d 1475 (Fed. Cir. 1994).

In this case, the cited patent fails as an anticipatory reference because it does not teach each and every element of the present claims. Specifically, Zimmerman does not teach fluidized beds, an adsorption medium in the form of particles having a density of at least 1.3 g/ml, or the placement of these particles in an adsorption column in the amount of at most 80% of the volume of the column.

The Examiner points to the coated plastic devices disclosed in column 4 of Zimmerman, at lines 45-65, asserting that these are stabilized fluidized beds. According to the passage in question, these devices were prepared in a manner that entails the coating and packing of the plastic beads, followed by the addition of a plasma sample, which is incubated in an agitator for one hour (see columns 3 and 4). Nowhere in these passages is a fluidized bed described, however. In fact, the Zimmerman commentary cannot relate to the fluidized beds as presently recited, since the treatment of the sample is the complete opposite of that for the sample in accordance with Applicants' claimed invention.

Fluidized beds are defined in the specification beginning at page 18, line 24. Such beds have reduced back-mixing due to a limited axial dispersion. Further, in the claimed method the sample is allowed to rise upward from a bottom inlet such that adsorbent medium is lifted from its settled state, and the sample (blood) is passed through the bed gently and without turbulence such that a large surface area of the adsorption medium is gently contacted with the sample. This upward rise of the sample without turbulence is a feature of fluidized

beds that provides superior efficiency of adsorption as compared to standard column chromatography, such as that described in Zimmerman.

The fact that Zimmerman does not disclose such fluidized beds, explicitly or inherently, is underscored in the description of agitating the sample (column 4, line 8), as well as the downward direction of the flow indicated by the arrows in Figures 1 and 2. Thus, the sample cannot rise upward and without turbulence, as it would in the fluidized beds of the present claims. Indeed, the packed columns of Zimmerman are not fluidized beds as required by the claims.

Zimmerman also does not disclose an adsorption medium in the form of particles having a density of at least 1.3 g/ml, nor the placement of these particles in an adsorption column in the amount of at most 80% of the volume of the column, as required in the claimed methods. The Examiner initially points to column 2, lines 44-46 of Zimmerman for disclosing both these limitations, but the identified passage does not in fact support such an assertion. This passage generically discusses using beads or hollow-fiber membranes, and if beads are used, they may be 10-500  $\mu\text{m}$ , packed in a perfusable packing in a column. The Examiner also points to the description in column 3, lines 19-25, but it likewise fails to disclose such characteristics.

In fact, no discussion of the density or particle volume in the column is found in these passages, or anywhere else in Zimmerman. Absent a showing to the contrary, there is no expectation that the columns of Zimmerman would share similar characteristics with those of the present invention due to their differing uses and physical requirements.

Accordingly, there is no teaching in Zimmerman of an adsorption medium in the form of particles having a density of at least 1.3 g/ml, nor the placement of these particles in an adsorption column in the amount of at most 80% of the volume of the column, as the present claims require. Zimmerman cannot anticipate those claims, therefore, and so Applicants respectfully request withdrawal of the rejection.

### **III. Jaber does not anticipate the claims**

Claims 2, 4-7, 9-10, 16-18, 20-23, and 26-27 are rejected over Jaber *et al.*, *Am. J. Kidney Dis.* (1997) 30:S44-S56 (“Jaber”), for alleged anticipation. Applicants respectfully traverse this rejection.

Like Zimmerman above, Jaber fails to disclose the use of fluidized bed adsorption columns in the present methods. As noted by the Examiner on page 9 of the Office Action, Jaber discloses hemoperfusion methods using fiber cartridges where the flow rate was 80-100 ml/min (page S50, 2<sup>nd</sup> col.) as well as flow rates in other packed columns with flow rates between 70-200 ml/min (page S53 generally). Nowhere in Jaber is there a discussion of fluidized bed adsorption columns as presently recited; nor is there an indication that anything other than a standard packed column is used. Indeed, the high flow rates suggest Jaber’s methodology is far removed from the gentle, fluidized adsorption of the presently claimed invention.

Jaber fails to teach the use of fluidized bed adsorption columns; hence, the reference cannot anticipate the present claims. Applicants therefore request withdrawal of this rejection.

### **IV. The present amendments address the Examiner’s objections**

The Examiner objected to claim 2 and its dependent claim for the informality of a typographical error in the delineation of the claim. This error has been corrected in the present amendment. Accordingly, Applicants request that the objection be withdrawn.

### **V. The claims are definite**

Claims 2 and 4-12 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly lacking proper antecedent basis in claim 2 for “the affinity specific molecule.” As this phrase now recites “an affinity specific molecule”, Applicants submit that the antecedent-basis issue is moot. Accordingly, Applicants request that the rejection be withdrawn.

### CONCLUSION

Applicants submit that this application is in condition for allowance, and favorable reconsideration is respectfully requested, therefore. Also, Examiner Hines is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account.

If any extension is needed for timely acceptance of submitted papers, then Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from Deposit Account No. 19-0741.

Respectfully submitted,

Date

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By

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